

USSN 09/616,283; Attorney Docket No. VRXB-P01-001

**DRAFT – NOT FOR ENTRY****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**In re Application of:  
GOODNOW, et al.

Serial No: 09/616,283

Filed: July 14, 2000

For: SYSTEM FOR DETECTING  
BACTERIA IN BLOOD, BLOOD  
PRODUCTS, AND FLUIDS OF  
TISSUES

Attorney Docket No. VRXB-P01-001

Art Unit: 1645

Examiner: J. Hines

*Binding Agent defined Pg 23 →  
→ pan-generic***Proposed claim amendments**

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1. **(Currently amended)** A method for screening for the presence of a clinically relevant amount of bacteria in donor blood or blood product from a donor mammal for transfer into a recipient mammal, comprising: contacting a sample of the donor blood or blood product with a set of pan-generic binding agents, wherein the set of pan-generic binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen and binding agents that specifically bind to a Gram-positive bacterial antigen, detecting binding of the set of binding agents to the sample, wherein binding indicates the presence of a clinically relevant amount of bacteria in the donor blood or blood product and no binding indicates the absence of a clinically relevant amount of bacteria in the donor blood or blood product from the donor mammal, wherein the blood or blood product determined to have an absence of a clinically relevant amount of bacteria is useful for transfer to the recipient mammal.
  2. **(Previously presented)** The method of claim 1, wherein the donor blood or blood product from the donor mammal determined to have an absence of a clinically relevant amount of bacteria is useful for transfer to a recipient mammal.
  3. **(Original)** The method of claim 1, wherein the donor blood or blood product is selected from the group consisting of whole blood, leukocytes, hematopoietic stem cells, platelets, red blood cells, plasma, and serum.

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4. (Original) The method of claim 1, wherein the binding agents that specifically bind to the Gram-negative bacterial antigen specifically bind to the lipopolysaccharide structure of the Gram-negative bacteria.
5. (Original) The method of claim 1, wherein the binding agents that specifically bind to the Gram-positive bacterial antigen specifically bind to the lipoteichoic acid structure of the Gram-positive bacteria.
6. (Original) The method of claim 1, wherein the set of binding agents is immobilized on a solid-phase support.
- 4 7. (Currently amended) A method for screening for the presence of a clinically relevant amount of Gram-positive bacteria in donor blood product from a donor mammal for transfer into a recipient mammal, comprising: contacting a sample of the donor blood or blood product with a set of pan-generic binding agents, wherein the set of pan-generic binding agents comprises binding agents that specifically bind to a Gram-positive bacterial antigen, detecting binding of the set of binding agents to the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-positive bacteria in the donor blood or blood product and no binding indicates the absence of a clinically relevant amount of Gram-positive bacteria in the donor blood or blood product, and wherein the donor blood or blood product from the donor mammal determined to have an absence of a clinically relevant amount of Gram-positive bacteria is useful for transfer to the recipient mammal.
- 8. (Currently amended) A method for screening for the presence of a clinically relevant amount of Gram-negative bacteria in donor blood product from a donor mammal for transfer to a recipient mammal, comprising: contacting a sample of the donor blood or blood product with a set of pan-generic binding agents, wherein the set of pan-generic binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen, detecting binding of the set of binding agents to the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-negative bacteria in the donor blood or blood product and no binding indicates the absence of a clinically relevant amount of Gram-negative bacteria in the donor blood or blood product, and wherein the donor blood or blood product from the donor mammal

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determined to have an absence of a clinically relevant amount of Gram-negative bacteria is useful for transfer to the recipient mammal.

9-13. (Canceled)

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14. (Currently amended) A method for screening for the presence of a clinically relevant amount of bacteria in a donor tissue from a donor mammal for transfer to a recipient mammal, wherein the donor tissue is stored in a fluid, comprising contacting a sample of the fluid with a set of pan-generic binding agents, wherein the set of pan-generic binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen and binding agents that specifically bind to a Gram-positive bacterial antigen, detecting binding of the set of binding agents to the sample, wherein binding indicates the presence of a clinically relevant amount of bacteria in the donor tissue and no binding indicates the absence of a clinically relevant amount of bacteria in the donor tissue, and wherein the donor blood or blood product from the donor mammal determined to have an absence of a clinically relevant amount of bacteria is useful for transfer to the recipient mammal.

15. (Previously presented) The method of claim 14, wherein the donor tissue determined to have an absence of a clinically relevant amount of bacteria is transferred to the second mammal.

16. (Original) The method of claim 14, wherein the donor tissue is selected from the group consisting of lung, heart, liver, skin, kidney, pancreas, spleen, and bone marrow.

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17. (Currently amended) A method for screening for the presence of a clinically relevant amount of Gram-positive bacteria in a donor tissue from a donor mammal for transfer to a recipient mammal, wherein the donor tissue is stored in a fluid, comprising contacting a sample of fluid with a set of pan-generic binding agents, wherein the set of pan-generic binding agents comprises binding agents that specifically bind to a Gram-positive bacterial antigen, detecting binding of the set of binding agents to the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-positive bacteria in the donor tissue and no binding indicates the absence of a clinically relevant amount of Gram-positive bacteria in the donor tissue, and wherein the donor blood or blood product from the donor mammal determined to have an

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absence of a clinically relevant amount of Gram-positive bacteria is useful for transfer to the recipient mammal.

18. (Currently amended) A method for screening for the presence of a clinically relevant amount of Gram-negative bacteria in a donor tissue from a donor mammal for transfer to a recipient mammal, wherein the donor tissue is stored in a fluid, comprising contacting a sample of the fluid with a set of pan-generic binding agents, wherein the set of pan-generic binding agents comprises binding agents that specifically bind to a Gram-negative bacterial antigen, detecting binding of the set of binding agents to the Gram-negative bacterial antigen in the sample, wherein binding indicates the presence of a clinically relevant amount of Gram-negative bacteria in the donor tissue and no binding indicates the absence of a clinically relevant amount of Gram-negative bacteria in the donor tissue, and wherein the donor tissue from the donor mammal determined to have an absence of a clinically relevant amount of Gram-negative bacterial is useful for transfer to the recipient mammal.

19-22. (Canceled)

23. (Previously presented) The method of any of claims 1, 7, 14, and 17, wherein the set of binding agents that selectively bind Gram-positive bacterial antigens is selected from the group consisting of an antibody, an antibiotic, mannose binding protein (MBP), Toll-Like Receptor 2 (TLR-2), and histatins.

24. (Canceled)

25. (Previously presented) The method of claim 23, wherein the antibiotic is polymixin or bacitracin.

26. (Previously presented) The method of any of claims 1, 7, 8, 14, 17, and 18, wherein the set of binding agents are detectably labeled with a reporter molecule.

27. (Previously presented) The method of claim 26, wherein said reporter molecule is selected from the group consisting of a molecule with enzymatic activity, a radio-labeled

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molecule, a fusion molecule, a fluorogenic molecule, a metal sol, a particle, a chromatic molecule, or a molecule that is specifically bound by a secondary agent.

28. **(Previously presented)** The method of any of claims 1, 7, 8, 14, 17, and 18, wherein the clinically effective amount of bacteria is greater than  $1 \times 10^7$  colony forming units per milliliter (CFU/ml) of blood or blood product.

29. **(Previously presented)** The method of any of claims 1, 7, 8, 14, 17, and 18, wherein the clinically effective amount of bacteria is greater than  $1 \times 10^6$  CFU/ml of blood or blood product.

30. **(Previously presented)** The method of any of claims 1, 7, 8, 14, 17, and 18, wherein the clinically effective amount of bacteria is greater than  $1 \times 10^5$  CFU/ml of blood or blood product.

31. **(Previously presented)** The method of any of claims 1, 7, 8, 14, 17, and 18, wherein the clinically effective amount of bacteria is greater than  $1 \times 10^4$  CFU/ml of blood or blood product.

32. **(Previously presented)** The method of any of claims 1, 7, 8, 14, 17, and 18, wherein the clinically effective amount of bacteria is greater than  $1 \times 10^3$  CFU/ml of blood or blood product.

33. **(Previously presented)** The method of claim 27, wherein the enzymatic molecule is selected from the group consisting of horseradish peroxidase, alkaline phosphatase, and  $\beta$ -galactosidase.

34. **(Previously presented)** The method of claim 26, wherein said reporter molecule is bound to the binding agent by intermolecular association.

35. **(Previously presented)** The method any of claims 1, 7, 8, 17, and 18 further comprising the step of transferring the blood or blood product to a recipient mammal.